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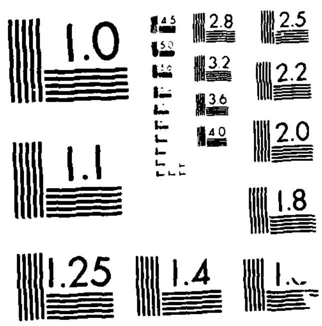

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APPLICATION OF ADVANCED MANUFACTURING TECHNIQUES TO FORGED SURGICAL INSTRUMENTS

AUGUST 1987

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Prepared for

Defense Logistics Agency
DLA-PR
Cameron Station
Alexandria, VA 22304-6100

Contract DLA 900-84-C-1508

DISTRIBUTION STATEMENT A
Approved for public release;
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A190 776

SECURITY CLASSIFICATION OF THIS PAGE

REPORT DOCUMENTATION PAGE

1a. REPORT SECURITY CLASSIFICATION Unclassified	1b. RESTRICTIVE MARKINGS
2a. SECURITY CLASSIFICATION AUTHORITY	3. DISTRIBUTION/AVAILABILITY OF REPORT Unclassified Distribution unlimited
2b. DECLASSIFICATION/DOWNGRADING SCHEDULE	
4. PERFORMING ORGANIZATION REPORT NUMBER(S) P06067-1	5. MONITORING ORGANIZATION REPORT NUMBER(S)
6a. NAME OF PERFORMING ORGANIZATION Cresap,McCormick and Paget Division of TPF&C Inc 6b. OFFICE SYMBOL (If applicable)	7a. NAME OF MONITORING ORGANIZATION Dr. Lloyd Lehn,Asst. for Manufacturing Technology OASD(A&L)PS/IR
6c. ADDRESS (City, State, and ZIP Code) 10 West 35th Street Chicago, IL 60616	7b. ADDRESS (City, State, and ZIP Code) Off. of the Asst. Secy of Defense Pentagon, Room 3C257 Washington, DC 20302-8000
8a. NAME OF FUNDING/SPONSORING ORGANIZATION Defense Logistics Agency 8b. OFFICE SYMBOL (If applicable) DLA-PR	9. PROCUREMENT INSTRUMENT IDENTIFICATION NUMBER DLA 900-84-C-1508
8c. ADDRESS (City, State, and ZIP Code) Cameron Station Alexandria, VA 22304-6100	10. SOURCE OF FUNDING NUMBERS PROGRAM ELEMENT NO. / PROJECT NO. / TASK NO. / WORK UNIT ACCESSION NO.

11. TITLE (Include Security Classification)
Application of Advanced Manufacturing Techniques to Forged Surgical Instruments

12. PERSONAL AUTHOR(S)
F. D. Seaman

13a. TYPE OF REPORT	13b. TIME COVERED	14. DATE OF REPORT (Year, Month, Day)	15. PAGE COUNT
Final	FROM ______ TO ______	August 1987	45

16. SUPPLEMENTARY NOTATION

17. COSATI CODES			18. SUBJECT TERMS (Continue on reverse if necessary and identify by block number)
FIELD	GROUP	SUB-GROUP	Surgical Instruments, Price differential, Machining, Polishing, Bench/assembly operation, Box lock, Lap joint, Precision casting, Show process, Forging, Cold forming,
06	12		

19. ABSTRACT (Continue on reverse if necessary and identify by block number)

The domestic industrial base for forged surgical instruments has been diminishing for more than 10 years. This erosion has reduced the industry to a point where it cannot meet surge requirements. These instruments are presently made in small batches using manufacturing methods that require large amounts of highly skilled labor. This study identified the operations that make up the manufacturing sequence. Operations can be divided into three categories, machining, benching/assembly and polishing. Aside from forging costs, these categories represent 25%, 25% and 50% respectively of the total manufacturing cost. The use of automated polishing and a non-flash net shape process to make the original starting piece, using Kelly forceps as an example, can eliminate most of the machining and polishing operations. A redesign of the hinge from a box lock to a lap joint would eliminate some of the bench/assembly steps. The net result would be to reduce manufacturing costs to a point where domestic forceps could compete with forceps made off-shore according to price differentials reported in the survey. Support for hinge redesign is documented. The applicability of such

20. DISTRIBUTION/AVAILABILITY OF ABSTRACT ☒ UNCLASSIFIED/UNLIMITED ☐ SAME AS RPT. ☐ DTIC USERS	21. ABSTRACT SECURITY CLASSIFICATION Unclassified
22a. NAME OF RESPONSIBLE INDIVIDUAL Robert A. Walk	22b. TELEPHONE (Include Area Code) 312/567-4730 22c. OFFICE SYMBOL

DD FORM 1473, 84 MAR   83 APR edition may be used until exhausted.
All other editions are obsolete.

SECURITY CLASSIFICATION OF THIS PAGE

18. Powder metallurgy.

19. net shape process candidates as precision casting, cold forming and powder metallurgy is considered.

IITRI-P06067-1

APPLICATION OF ADVANCED MANUFACTURING TECHNIQUES TO FORGED SURGICAL INSTRUMENTS

(Final Report - Planned Producer Survey)

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FOREWORD

The domestic industrial base for forged surgical instruments has been diminishing for more than 10 years. This erosion has reduced the industry to a point where it cannot meet surge requirements, which are over 1500 percent of peacetime requirements. These instruments are presently made in small batches using manufacturing methods that require large amounts of highly skilled labor. This study identified the operations that make up the manufacturing sequence. Once identified the operations were evaluated and it was determined that several advanced manufacturing techniques might improve productivity to a point where the domestic industry could compete on price with offshore sources. Such an ability to compete worldwide might halt the decline of the domestic base and, ultimately strengthen it enough to ensure a reliable surge capacity.

This report documents the results of a special task funded by the Defense Logistics Agency (DLA-PR - Mr. D. Gearing) under the MTIAC contract DLA 900-84-C-1508. Contract line item 0001AD "Application of Advanced Manufacturing Technology Techniques to Forged Surgical and Dental Instruments". The study was conducted between 29 Jan 1987 and 11 Jul 1987. Dr. M. A. H. Howes was IITRI program manager. F. D. Seaman acted as principal investigator. Special recognition is made of the contribution of Mr. N. Gewertz, Chief of Industrial Preparedness Planning for Medical Material at the Defense Personnel Support Center, who provided the industry contacts and valuable insight concerning status of the industry. The project team also wishes to acknowledge the manufacturers who cooperated in the survey:

Codman and Shurtleff Inc, Randolph MA
Columbia Surgical Instruments, Brooklyn NY
Larry Appolito Co, Irvington NJ
Michigan Instrument Corp, East Orange NJ
Pilling Company, Ft. Washington PA
Schilling Forge, Syracuse NY
Edward Weck and Co, Research Triangle Park NC

Approved by

M. A. H. Howes
Special Task Manager

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F. D. Seaman
Principal Investigator

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1. BACKGROUND

The domestic industrial base for forged surgical and dental instruments has been diminishing for more than 10 years. These instruments are handmade in small batches and require a great deal of skill and training to manufacture. The base cannot meet the tremendous surge requirements, which are over 1,500 percent of peacetime requirements. To protect the industrial base, the Defense Logistics Agency has granted the Defense Personnel Support Center (procuring activity for these items) the authority to restrict competition to planned producers (Table 1). A complimentary effort is to develop advanced manufacturing technology and encourage its use by the industry to lower costs and increase international competitiveness.

2. DESCRIPTION AND SCOPE OF WORK

This project reviewed forged surgical and dental instrument manufacturing processes commonly used in the industry, considered reduced costs as a means for strengthening the industrial base, identified areas where advanced technology might reduce costs, and described research needs and economic benefits for the new technologies. Alternative strategies for developing and implementing advanced technology are also discussed.

3. REVIEW OF MANUFACTURING PROCESSES USED IN THE INDUSTRY

A survey of the Federal Supply Catalogue Number 6515 Medical and Surgical Instruments, Equipment and Supplies suggests that forged instruments fell into three manufacturing groups.

Group 1: Ring finger hand tools. This includes forceps, needle holders (Figure 1) and scissors (Figure 2).

Group 2: Tweezer hand tools (thumb forceps): Very few of these (Figure 3) are made by planned producers.

Group 3: Miscellaneous: For the most part these are represented by collections of subcomponents. The retractors in Figure 4 are typical of this group.

TABLE 1. PLANNED PRODUCERS

FIRM	ITEM
A&P Surgical Irvington, NJ	Scissors & Forceps
Codman & Shurtleff* Randolph, MA	Forceps & Suture Needle Holders
Columbia Surgical* Instrument Co. Brooklyn, NY	Forceps & Suture Needle Holders
Michigan Instr. Corp.* East Orange, NJ	Scissors, Forceps & Suture Needle Holders
American V. Mueller Chicago, IL	Forceps & Suture Needle Holders
Pilling Company* Fort Washington, PA	Forceps & Suture Needle Holders
J. Sklar Mfg. Co. Long Island, NY	Forceps & Suture Needle Holders
Post Surgical Instrument Co. Farmingdale, NY	Retractors
Edward Weck & Co.* Durham, NC	Forceps & Suture Needle Holders
Larry Appolito Co.* Irvington, NJ	Scissors
Grieshaber Mfg. Co. Norridge, IL	Forceps, Rongeurs & Retractors
Hu-Friedy Mfg. Co. Chicago, IL	Dental Forceps & Rongeurs
International Scissors Ltd. Perth, Ontario, Canada	Scissors

*Visited during program.

Source DLA/DPSC

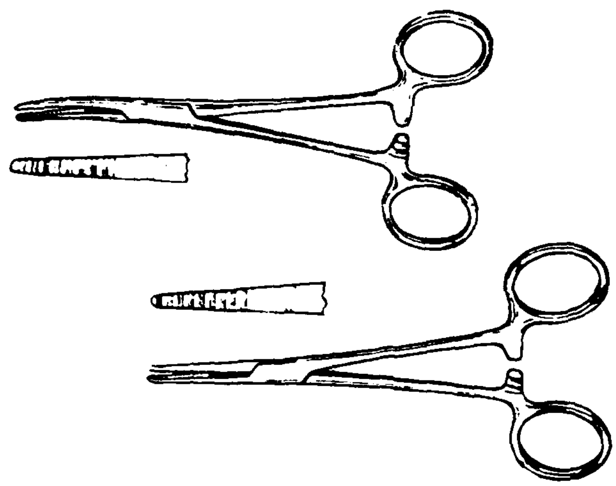

Figure 1. Typical forceps (5-1/2 inch, Kelly - straight and curved)

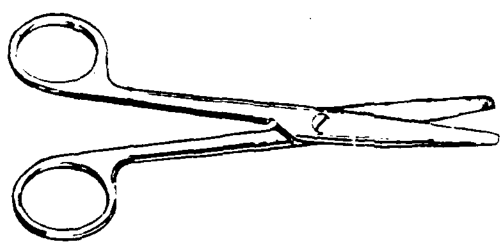

Figure 2. Typical surgical scissors (7 inch - straight)

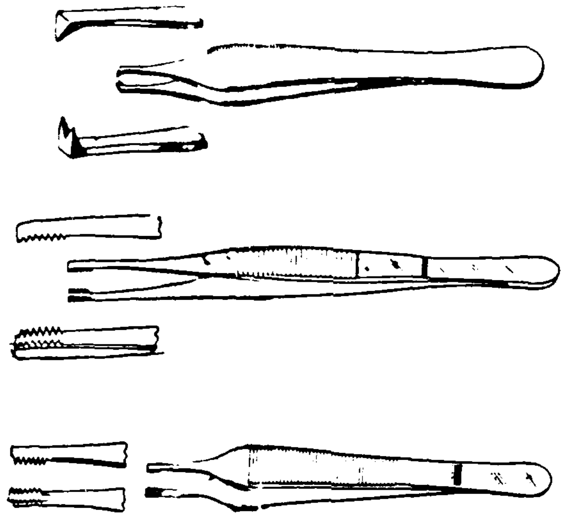

Figure 3. Tweezer forceps (Top: Adson; Middle: Brown; Bottom: Adson-Brown)

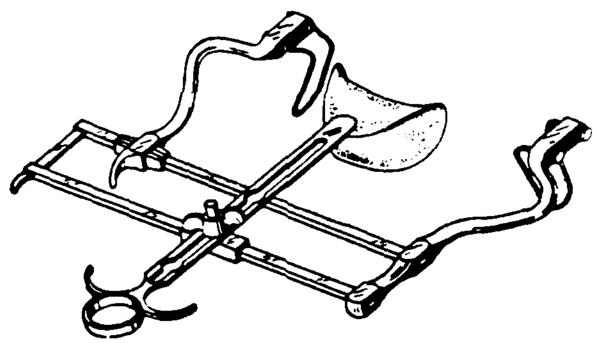

Figure 4. Miscellaneous equipment (abdominal retractor)

Within the $4,160,640 procurement of hand held surgical instruments listed in ref. 1, Group 1, ring finger configurations represent $3,329,723. At least two of the planned producers indicated that they concentrate all of their efforts on ring finger configuration. Because of the prevalence of the ring finger family throughout the planned producer community, the review of manufacturing practices focused on this configuration.

All ring finger (Group 1) instruments are presently made from forgings (Figure 5). A martensitic stainless steel is specified for both forceps and scissors. Forceps are made from a grade containing 0.16-0.25 percent carbon. This grade is hardened during the manufacturing sequence to Rc 40-46 (VHN 390-485). The cutting edge of scissors demands an alloy containing 0.26-0.55 percent of carbon because they must be hardened to Rc 50-58.

Once the forging is available, three processes are applied to produce the finished tool. These processes are:

1. Machining
2. Assembly and Benching
3. Polishing (including electropolishing)

Two metallurgical processes are also applied to meet quality requirements:

1. Hardening
2. Passivation

3.1 MACHINING

Forgings (Figure 5) are close to final contour and contain many of the compound curved surfaces that will make up the final instrument.

The principal use of machining is in the production of the hinged joint (Figure 6). There are two hinge configurations:

1. Box: Used for all tools except scissors and those forceps that are used only for such operating room chores as handling towels. The box joint provides a very stable closing action between the jaws where lateral shifting could cause tissue damage.

2. Lap: Scissor blades are designed to shift during closing. The closing action of scissors is controlled by the set of the blades and a subtle contouring of the mating surface called a "ride". The costly box configuration is not applicable to scissors.

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Figure 5. Starting blank (top) and untrimmed forging (for a small needle holder)

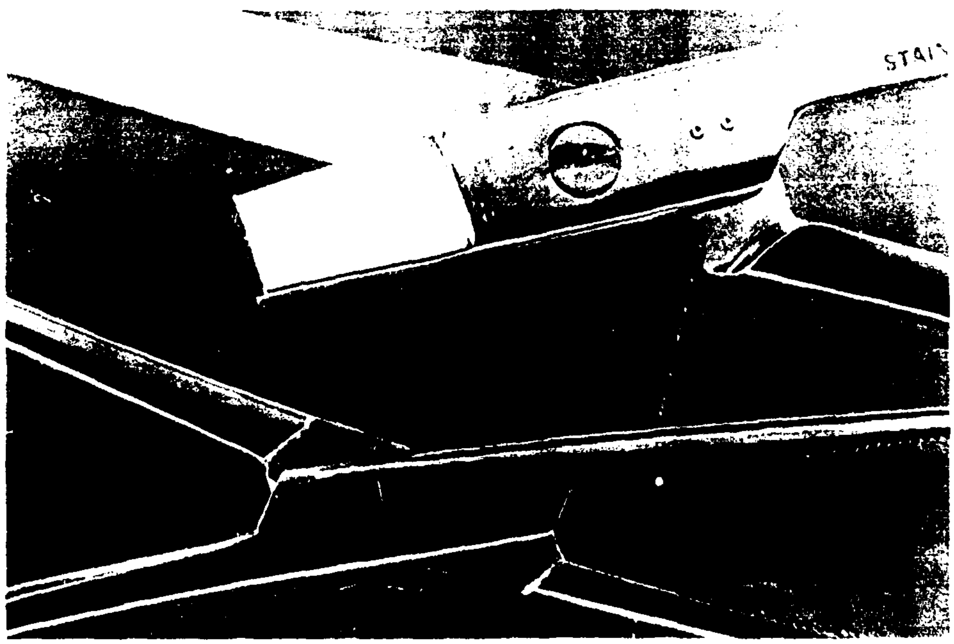

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Figure 6. Hinged joints (lap joint - top) (box lock - bottom)

Hinged joint machining operations include formation of the male and female box lock configurations (Figure 7), formation of serrations or other gripping details on the jaw of clamps (Figure 8), establishment of the mating surfaces and shoulders of the lap joint (Figure 9), establishment of the inside shanks on scissors (Figure 10), and drilling (or drilling and tapping in the case of scissors) to place the hinge pin (Figure 11).

Machining operations are followed by deburring. Deburring usually involves a rotating brush, but at least one company uses electropolishing in the deburr mode.

Machining operations are carried out on the annealed (softened) forging and are completed prior to the hardening operation that occurs approximately midway in the operational lineup.

3.2 BENCHING OPERATIONS AND ASSEMBLY

Benching is the term used for the bending and twisting that is applied to instruments throughout the manufacturing sequence in order to convert the shape of the rough formed forging into its final configuration. Benching requires a great deal of operator skill. It is a manual operation using only simple tools. Bending forcep jaws to meet the drawing configuration is an example of a bench step and is usually accomplished in a simple, universal three-pin fixture mounted on a workbench. In the final stages of manufacture benching may involve a hammering to adjust the degree of jaw closure in terms of the lock position of the handles. Adjusting the degree of engagement of scissor blades ("setting the blades") is a benching operation that is unique to scissors.

Assembly is a special benching operation that is used to insert the male through the female slot in the box lock configuration. After the slot has been machined the female component must be subjected to significant plastic transverse distortion in order to allow the male jaw and shoulder to pass through until the serration in the jaws interdigitate. (Figure 12) The female slot is then closed. This opening and closing operation on the slot disrupts any alignment or clearances that had been previously established and undoubtedly sets up stresses that cause distortion during heat treatment.

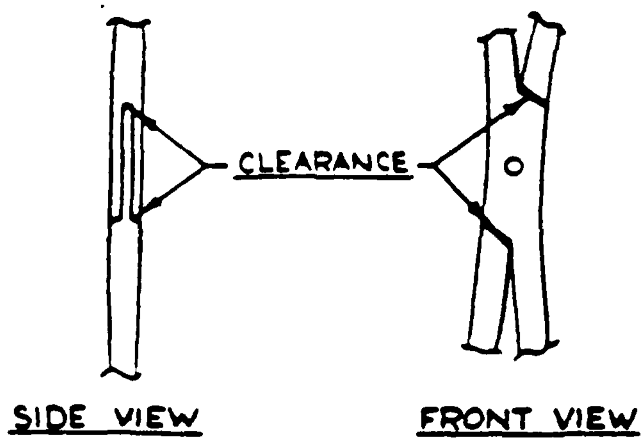

Figure 7. Box lock detail

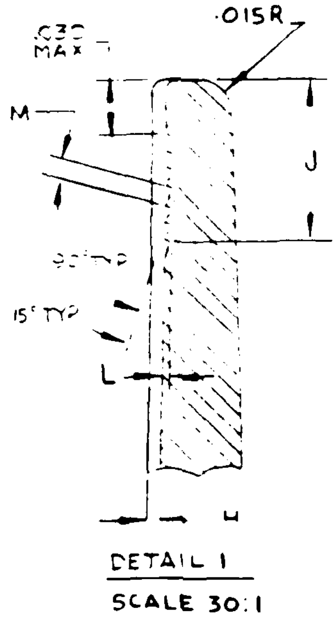

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Figure 8. Serration detail

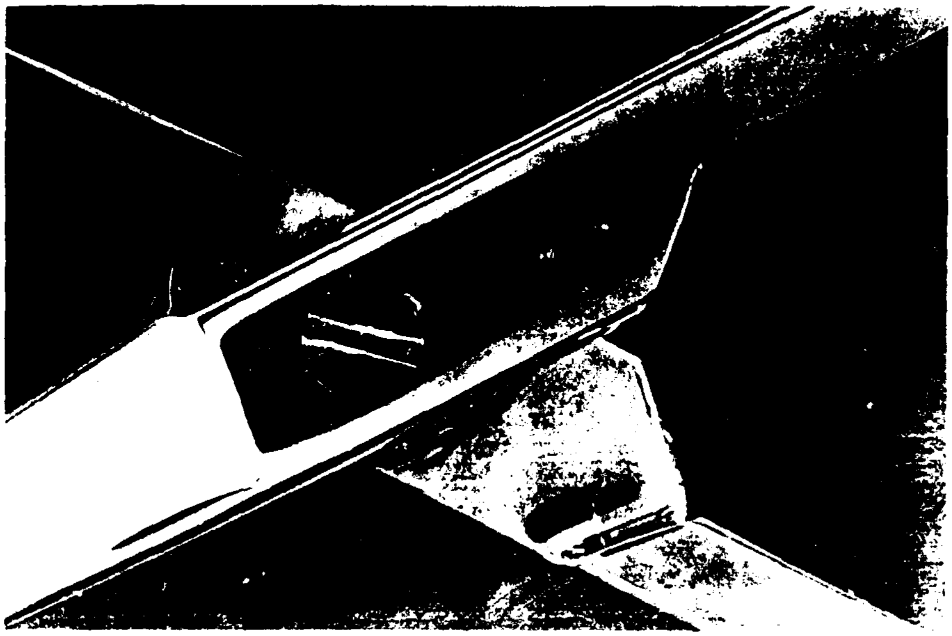

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Figure 9. Lap joint detail

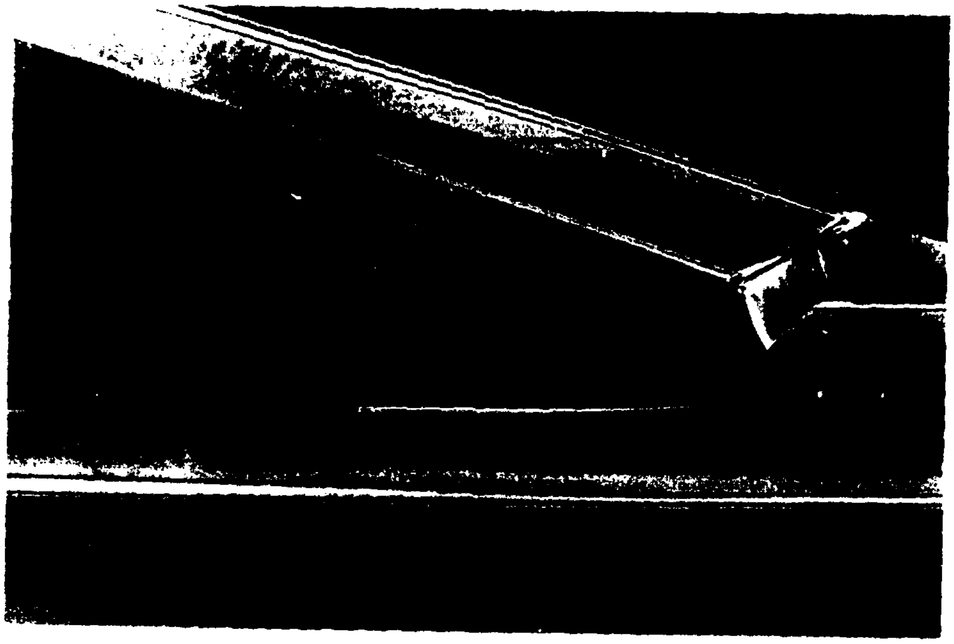

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Figure 10. Inside shank and shoulder contour (scissors)

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Figure 11. Hinge pin hole & pin (box lock construction)

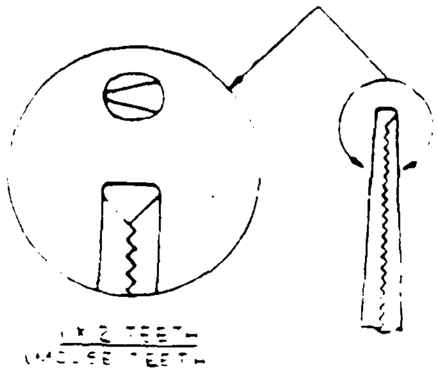

Figure 12. Interdigitation of teeth and serrations
(prior to pinning the box lock)

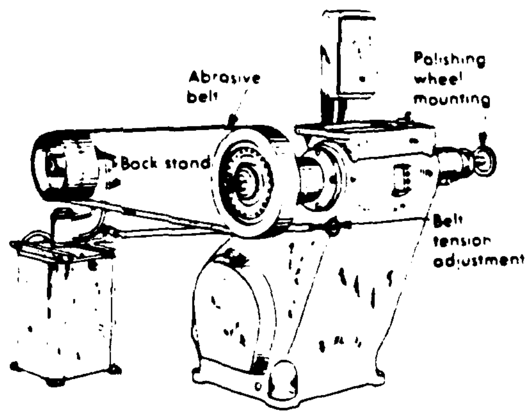

Figure 13. Typical abrasive belt machine
(with polishing/buffing wheel)

After closing the slot, the part is brought to shape and, with any serrations interdigitated, drilled for the hinge pin. Subsequently the pin is also plastically upset into the drilled hole or otherwise secured. Securing the pin also creates internal stress in the metal and a further potential for distortion after heat treatment.

Most manufacturers set tools with a box lock hinge three times during their manufacture:

1. "Soft" set to shape the jaws and correct deformation caused by assembly.

2. "Hard" set to correct distortion from heat treating. Heat treat distortion comes from:

   a. relief of assembly and soft set stress upon heating to the austenitizing temperature (about 1600°F).

   b. stresses set up as the steel changes volume at various points in the assembly during quenching.

   c. thermal twisting as sections heat or cool nonuniformly.

3. "Final" set to correct distortion after hard set and when all grinding and buffing are complete. Distortions after hard set occurs when:

   a. stressed metal is removed locally by polishing.

   b. thin sections are heated in polishing or grinding.

The box lock represents some significant implications for any application of advanced technology because its assembly demands so much distortion. Thus it would seem that some benching will always be needed to account for deformation in box lock assembly. Similarly some machining will always be required to locate the pin hole after the jaw serrations have been interdigitated (Figure 12). In all likelihood some machining will always be required in conjunction with net shape forming to form the rectangular female portions of the lock.

These same restrictions do not apply to scissors where the simpler lap joint can be used. A pin hole tapping operation and setting of the scissor blades are all that would be required. In fact, the use of the lap joint permits scissors to be made with only one final benching after setting of the blades.

The above suggests that considerable handwork and rework could be eliminated if a lap joint could be substituted for box joints. The substitute lap joint would have to be considerably more stable with respect to jaw closure then the highly flexible scissor joint.

3.3 POLISHING

The forgings (Figure 5) are close to final contour and contain many of the compound curved surfaces that will make up the final instrument. Irregularities, such as flash that remain after trimming, are removed by abrasive operations. Most of the planned producer organizations that were interviewed included these abrasive operations under polishing. This is a reasonable approach. The effort required to achieve a desired surface finish at any point of the manufacturing sequence is directly related to the marks left by the preceding operations. Thus, it is reasonable to include the initial belt grinding operations in the polishing scheme even though their purpose is to machine residual forging flash, cut flat surfaces in the contoured forging or even reshape the jaws of the individual forceps or needle holders so that several styles can be made from one, common forged shape. Most of these operations are conducted against the idler wheel of an abrasive belt machine (Figure 13). Where possible, scratches run parallel to the axis of the instrument.

There is a second type of operation that is carried out on abrasive belts where the part is fed into the belt between the drive wheel and backstand shown on Figure 13. This form of abrasive grinding permits the unsupported belt to follow rounded contours and is called "strapping". Strapping, is necessary to blend the basic curvature of the parts, with the contour irregularities generated by the initial abrasive machining steps. By definition, strapping is done at right angles to the axis of the instrument. Abrasive smoothing proceeds most rapidly when each step scratches the surface at right angles to the preceding step.

Abrasive operations usually proceed in steps of 30 grit numbers (e.g., 60-90-120-180-220). However, at least one producer is proceeding in steps of 60 grit numbers. Grit sizes are inverse to the grit numbers and it is conventional to reach 220 grit before initiating the two-stage buffing operations.

Traditionally surgical instruments are sold in a buffed condition. This means that a soft polishing compound is placed on a cloth wheel and applied to surfaces that are already quite smooth. Initially the part is moved against the wheel motion to force the compound to "cut in" microscratches that act as an optical grating - reflecting only selected wave lengths of light at any given angle of viewing. Such marks, however, tend to make the part look dark. Thus the part is next moved in the direction of the wheel rotation to bring back some of the brightness by superimposing scratches that are too fine to act as a grating.

More recently matt finishes have been accepted. These are produced by impinging an airborne stream of particles on the surface. Usually glass beads are used to produce a light rounded impression.

Another recent innovation is the introduction of mass finishing. In mass finishing, unfinished parts are mixed with abrasive shapes and moved together in a container. Vibratory motion seems to be preferred because the parts do not strike each other as they do if the mixture is placed in a rotating barrel. The investigation could not determine exactly which abrasive steps were eliminated but it is likely that vibratory polishing eliminates the 60 to 120 range of abrasives and produces a surface that can then be matt finished or subjected to some final polishing/buffing.

Electropolishing as a final surface finishing step may be in use, but none of the producers indicated such an application. Most producers said their tests had resulted in an irregular or pitted finish. One producer admitted to using the process in its deburring mode. Another noted that electropolishing was used in Germany as a final finish but indicated that the technology was too costly. This is probably a correct assessment because proper electropolishing often requires some part-specific development which smaller companies could ill afford.

3.4 SEQUENCE OF MANUFACTURING OPERATIONS

Each of the above operations is used in a specific sequence in order to produce an instrument. Table 2 suggests a sequence that would apply to most of the producers that were visited. The sequence is not rigidly followed throughout the community and producers may vary some steps to accommodate plant layout or work load. The sequence emphasizes the difference between forceps and scissors.

3.5 RELATIONSHIPS BETWEEN MANUFACTURING OPERATIONS AND COSTS

In subsequent discussion of cost reductions as a means for strengthening the industrial base it is important to note the reported relationship between operations and cost.

Note that not each of the above manufacturing operations offers the same possibility for savings because cost is not distributed equally among them. At least two planned producers noted that the manufacturing costs were distributed as follows:

Machining:	25%
Assembly/Bench:	25%
Polishing:	50%

Direct questions regarding the cost of specific operations were not included in interviews with producers because the answers, if any, would have revealed proprietary information. One supplier redefines some early abrasive operations and arrives at a 33:33:33 ratio but most suppliers defined the process as noted and used the above ratio.

4. REDUCED COSTS AS A MEANS FOR STRENGTHENING THE INDUSTRIAL BASE

As noted in Section 1 this study was prompted by the erosion of the industrial base for forged surgical instruments. Underpricing by foreign competition is a major cause for the erosion of the industrial base for surgical instruments. Cost reductions represent the most direct way to attack underpricing. Therefore a method for dealing with costs and cost reduction in a nonproprietary manner was developed using the manufacturing sequence and generalized process/cost relationships developed in Part 3. The first task was to expand the manufacturing sequence set forth in Table 2 to delineate which steps fell into the three process categories for which generalized costs were available (i.e., machining, bench/assembly and

TABLE 2. SIMPLIFIED MANUFACTURING SEQUENCE
(for forceps & scissors - mirror finish)

BASIC MANUFACTURING SEQUENCE

Forging Sequence

Shear Forging Blank

Forge
Anneal
Trim Flash

Instrument Manufacturing Sequence

Remove Remaining Flash
Blend Compound Curves
Strap Over Outer Surface
Strap Inside Rings

Forcep Joint Sequence

Undercut Lock
Machine Jaw Flat
Serrate Jaw End
Contour Jaw Tip
Machine Male Flat/Shoulder
Repeat Opposite Side
Broach Slot)
Spread and Assemble
Close and Align
Drill and Pin
Set (soft)

Scissors Joint Sequence

Machine Shanks/Shoulder
Machine Inside Blade
Set Blade (soft)
Edge Blade
Drill, Tap, and Pin

Basic Manufacturing Sequence (continued)

Harden
Set/Adjust (Hard)
Polish 60 Grit[1]
Polish 90
Polish 120
Polish 150
Polish 180
Polish 220
Buff Cut Down [2]
Buff Color [2]
Set Final
Passivate [3]
Test
Package

[1] Some polishing steps may be accomplished by mass (vibratory) finishing
[2] A matt finish may be required in place of polishing. Matt finishing involves bead blasting.
[3] Electropolishing is an acceptable substitute. Electropolishing is also used for smoothing and deburring.

polishing). The second task was to establish a cost reduction goal that would wipe out any cost differential with foreign products. If the cost of U.S. instruments could be reduced to overcome this differential they would be more attractive domestically. The U.S. instruments could also compete abroad. Both actions would strengthen the industrial base. The third task would be to test various advanced technologies against the process/cost implications of the expanded manufacturing sequence. The third task would then identify those technologies that might eliminate enough steps to meet the cost reduction goal. The third task is described in Part 5.

4.1 EXPANDED MANUFACTURING SEQUENCES

Tables 3 and 4 set forth the expanded sequence. These tables also note the reason(s) behind the inclusion of each operation. According to Table 3 the manufacture of forceps involves thirty-three operations. Eleven operations are considered machining, four represent manual benching or assembly operations and eighteen form the polishing sequence. Among the most commonly cited reasons for the operations are:

1. Eliminating metal (mostly flash) that did not take the required shape during forging (eight operations).

2. Establishing closer tolerances and greater detail than is possible during forging (ten operations).

3. Compensating for prior surface finishing (eight operations).

4. Machining and assembling the box lock plus subsequent compensation for the distortion involved (seven operations).

The manufacture of scissors involves only twenty-six operations because the complex machining and assembly of the box lock is not required. The manufacturing of scissors was divided (Table 4), into five machining operations, three assembly and benching operations and eighteen polishing operations. The reasons behind these operations are similar to those noted for forceps, except for the operations related to the box lock on the forceps.

The detailed manufacturing sequences of the various producers would be somewhat more elaborate than those used for the preceding analysis. Producers noted that forty to fifty operations are involved in the manufacture of a forcep instead of thirty-three. It is likely that many of the early contour-restoring operations, for example, are subdivided to permit abrasive equipment to match

TABLE 3. ANALYSIS OF MANUFACTURING SEQUENCE FOR FORCEPS

OPERATION	MACHINING	BENCH/ASSY	POLISH	REASON FOR OPERATION
Remove Remaining Flash			2*	Eliminate metal that did not take required surface contour
Blend Compound Curves			2	Eliminate metal that did not take required surface contour
Strap Over Outer Surface			2	Eliminate metal that did not take required surface contour
Strap Inside Rings			2	Eliminate metal that did not take required surface contour
Undercut Lock	2			Establish more complex contour than can be forged
Machine Jaw Flat	2			Establish closer tolerances than can be forged
Contour Jaw End			2	Adopt a generic forging to the shape and dimensions of a specific part
Serrate Jaw End	2			Establish more complex contour than can be forged
Male Flat & Shoulder	1			Establish closer tolerances than can be forged
Repeat Opposite Side	1			Establish closer tolerances than can be forged
Pilot Female Box	1			Establish more complex contour than can be forged
Broach Female Box	1			Produce a narrow, deep thru-part penetration parallel to die plane
Spread and Assemble		1		Produce a temporary shape change
Close and Align		1		Restore shape
Drill Pin	1			Establish hinged movement
Set (soft)		1		Establish functional relationship with serrations aligned
Harden				Meet required properties
Set (Hard)		1		Correct for movement during hardening
Polish 60 Grit			1	Compensate for prior surface scale/descale and grinding operations
Polish 90 Grit			1	Compensate for 60 grit
Polish 120 Grit			1	Compensate for 90 grit
Polish 150 Grit			1	Compensate for 120 grit
Polish 180 Grit			1	Compensate for 150 grit
Polish 220 Grit			1	Compensate for 180 grit
Buff Cut Down			1	Compensate for 220 grit
Buff Color			1	Establish "Color"
TOTAL OPERATIONS	11	4	18	

* One operation on each blade

TABLE 4. ANALYSIS OF MANUFACTURING SEQUENCE FOR SCISSORS

OPERATION	MACHINING	BENCH/ASSY	POLISH	REASON FOR OPERATION
Remove Remaining Flash			2*	Eliminates metal that did not take required surface contour
Blend Compound Curves			2	Eliminates metal that did not take required surface contour
Strap Over Outer Surface			2	Eliminates metal that did not take required surface contour
Strap Inside Rings			2	Eliminates metal that did not take required surface contour
Machine Shank/Shoulder	2			Establish a closer tolerance contour than can be forged
Machine Inside Blade	2			Establish a closer tolerance contour than can be forged
Set Blade Curvature		2		Establish a more complex contour than can be forged
Edge			2	Establish a closer tolerance edge than can be forged
Pin	1			Establish hinged movement
Harden				Meet required properties
Adjust		1		Establish a functional cutting relationship with pin in place
Polish 60 Grit			1	Compensate for prior surface scale/descale & grinding operations
Polish 90 Grit			1	Compensate for prior 60 grit
Polish 120 Grit			1	Compensate for prior 90 grit
Polish 150 Grit			1	Compensate for prior 120 grit
Polish 180 Grit			1	Compensate for prior 150 grit
Polish 220 Grit			1	Compensate for prior 180 grit
Buff Cut Down			1	Compensate for prior 220 grit
Buff Color				Establish "color"
TOTAL OPERATIONS	5	3	18	

*One operation on each blade

the several contours involved in each tool. However, it is believed that the simplified sequence established in this study can be used to evaluate the potential for cost reduction through elimination of the steps.

4.2 COST REDUCTION GOAL

The survey of planned producers revealed that instruments from Pakistan sold for about one-half the price of U.S. instruments of a similar grade. Comparative prices are listed in Table 5. The lowest cost U.S. instrument in Table 5 is $5.00 and its Pakistani counterpart is $2.50. The $2.50 differential is the very least cost that must be removed by any new manufacturing technology. According to interviews with the planned producer community a pair of forgings for an instrument such as the Kelly Forcep listed in Table 5 costs at least $1.20. Once an allocation of $1.20 is made to obtain the two forgings that make up the instrument, only $3.80 remains of the total instrument cost. The $3.80 remainder represents the cost of machining, assembly/bench and polishing operations (with their overhead and profit components). The $2.50 price differential must be accounted for by cost reductions in each of these operations.

4.3 TESTING THE IMPACT OF ADVANCED TECHNOLOGY

A review of the reasons for many of the operations in the manufacturing sequence (Tables 3 and 4) reveals several basic needs that must be met by any advanced technology that is to be tested for its effect on the manufacturing sequence.

1. Need for a near net shape process that would not require the removal of flash and which would be flexible enough to make one specific starting configuration for each individual instrument without excessive retooling.

2. An additional need for the following refinements (listed in order of increasing advancement beyond present net shape forming practice):

   (a) establishment, during initial forming, of a 220 grit finish ready for buffing or bead blasting.

   (b) ability to produce dimensional shapes equivalent in precision to presently machined shapes such as shoulders, shanks and the male box slot configuration.

   (c) ability to produce details such as serrations and ratchet undercut.

TABLE 5. REPORTED COMPETITIVE PRICES
(Kelly forcep or equivalent)

Source	Pakistan[1] Price	United States[2] Price
Planned Producer A	\$2.45	\$6.00[4]
Planned Producer B	\$2.50[3]	\$5.00-5.50
Planned Producer C	\$2.50	\$5.00

1 Wages reported as \$3.50 to \$7.00 per day

2 Wages reported as \$56 to \$126 per day (including fringes)

3 Quality and performance similar to U.S. and German instruments. Lower quality substitutes may sell for \$1.40

4 Planned Producers note that a pair of forgings cost \$1.00 to \$1.20 for small tools.

(d) introduction of the box slot opening ready for broaching.

(e) refinement of (d) to produce the finished female box slot configuration.

3. An automatic method for producing the (colorized) mirror finish.

4. A substitute joint for the box lock that would not sacrifice the vital jaw alignment and clamping stability associated with the box configuration.

The impact on the manufacturing sequence as a result of meeting some, or all of the above needs was considered in Tables 6 and 7. The left hand columns repeat the operational sequences established in Tables 3 and 4 for forceps and scissors respectively. The remaining columns tabulate the cumulative reduction in manufacturing steps as each need is met. At the bottom of the tables is shown the percentage of each process type that is eliminated as progressively more complex needs are met.

4.4 CONVERTING SEQUENCE IMPACT TO COST REDUCTION

Using the example of the Kelly forceps cited in Section 4.2, the 25:25:50 relationship among machining, bench/assembly and polishing can be converted to cost as follows:

Total Cost		\$5.00
Cost, Material (pair of forgings)		\$1.20
Cost Balance (B) of Manufacturing Operations		\$3.80
Breakdown of Balance of Manufacturing (B)		
Machining (25% B)	=	\$0.95
Bench/Assembly (25% B)	=	\$0.95
Polishing (50% B)	=	\$1.90
		\$3.80
Cost Reduction Goal		\$2.50

Tables 8 and 9 accomplish a preliminary conversion of impact (in terms of percentage of steps removed by the fulfillment of progressively more complex needs) into manufacturing cost reductions that might be used to offset the \$2.50 competitive differential.

TABLE 6. IMPACT OF ADVANCED TECHNOLOGY ON MANUFACTURING SEQUENCE FOR FORCEPS

OPERATION	MACHINING	BENCH/ASSY	POLISH	Operations Eliminated by the Flexible No-Flash Net Shape Processes: A Basic** Process			B Plus 220Grit Finish			C Plus Machine Tool Precision			D Plus Detail and Undercut			E* Plus Slot Config.			F* Plus Machined Slot Precision			G Auto. Finish (Color)			H Substitute For Lock Box		
				M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P
Remove Remaining Flash			2			2			2			2			2			2			2			2			2
Blend Compound Curve			2			2			2			2			2			2			2			2			2
Strap Over Outer Surf			2			2			2			2			2			2			2			2			2
Strap Inside Rings			2			2			2			2			2			2			2			2			2
Undercut Lock	2												2			2			2			2			2		
Machine Jaw Flat	2									2			2			2			2			2			2		2
Contour Jaw End			2			2			2			2			2			2			2			2			2
Serrate Jaw End	2									2			2			2			2			2			2		
Male Flat & Shoulder	1									1			1			1			1			1			1		
Repeat Opposite Side	1									1			1			1			1			1			1		
Pilot Female Box	1															1			1			1			1		
Broach Female Box	1															1			1			1				1	
Spread and Assemble		1																									
Close and Align		1																								1	
Drill Pin	1																										
Set (Soft)		1																								1	
Harden	-	-	-																								
Set (Hard)		1																									
Polish 60 Grit			1						1			1			1			1			1			1			1
Polish 90 Grit			1						1			1			1			1			1			1			1
Polish 120 Grit			1						1			1			1			1			1			1			1
Polish 150 Grit			1						1			1			1			1			1			1			1
Polish 180 Grit			1						1			1			1			1			1			1			1
Polish 220 Grit			1						1			1			1			1			1			1			1
Buff Cut Down			1																					1			1
Buff Color			1																					1			1
Total Removed in Mfg. Sequence	-	-	-	0	0	10	0	0	16	4	0	16	8	0	16	9	0	16	10	0	16	10	0	18	10	3	18
Total in Mfg. Sequence	11	4	18			18			18	11		18	11		18	11		18	11		18	11		18	11	4	18
Percent Removed						56			77	36		77	72		77	81		77	91		77	91		100	91	75	100

Notes:
(*) If Lock substitute pursued, Col. E&F need not be pursued because these operations would be eliminated from manufacture
(**)Refers to the three types of manufacturing operations:
M=Machining
B/A=Bench/Assembly
P=Polish

TABLE 7. IMPACT OF ADVANCED TECHNOLOGY ON MANUFACTURING SEQUENCE FOR SCISSORS

Operations Eliminated by the Flexible No-Flash Net Shape Processes

OPERATION	MACHINING	BENCH/ASSY	POLISH	A Basic Process			B Plus 220Grit Finish			C Plus Machine Tool Precision			D Plus Detail and Undercut			E Plus Slot Config.			F Plus Machined Slot Precision			G Auto. Finish (Color)			H Substitute For Lock Box			REMARKS
				M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	M	B/A	P	
Remove Remaining Flash			2			2			2			2			2									2				
Blend Compound Curves			2			2			2			2			2									2				
Strap Over Outer Surf			2			2			2			2			2									2				
Strap Inside Ring			2			2			2			2			2									2				
Machine Shank/Shoulder	2									2			2									2						
Machine Inside Blade Flat	2												2									2						
Set Blade Curvature		2																										
Edge			2													Not			Not						Not			
Pin	1															Applicable			Applicable						Applicable			
Harden	-	-	-																									
Adjust		1																										
Polish 60 Grit			1						1			1			1									1				
Polish 90 Grit			1						1			1			1									1				
Polish 120 Grit			1						1			1			1									1				
Polish 150 Grit			1						1			1			1									1				
Polish 180 Grit			1						1			1			1									1				
Polish 220 Grit			1						1			1			1									1				
Polish Cut Down			1																					1				
Polish Color			1																					1				
Total Removed in Mfg. Sequence	-	-	-	0	0	8	0	0	14	2	0	14	4	0	14							4	0	16				
Total in Mfg. Sequence	5	13	18			18			18	5		18	5		18							5		18				
Percent Removed						44			77	40		77	80		77							80		88				

TABLE 8. COST REDUCTION FOR FORCEPS
(preliminary estimate)

Item (refers to columns in Table 5)	Need Fulfilled	Cost Savings: Machining ($0.95/unit (%)	Cost Savings: Machining ($0.95/unit ($)	Cost Savings: Bench and Assemble ($0.95/unit (%)	Cost Savings: Bench and Assemble ($0.95/unit ($)	Polish ($1.90/unit) (%)	Polish ($1.90/unit) ($)	Total $
	I. Flexible No-flash Net Shape Process (progressive accumulation A-E)							
A	Basic Process	-	-	-	-	56	1.06	1.06
B	220Grit Finish	-	-	-	-	77	1.46	1.46
C	Machined Surfaces	36	0.34	-	-	77	1.46	1.80
D	Detail & Undercut	72	0.68	-	-	77	1.46	2.14
E*	Slot Configuration	81	0.77	-	-	77	1.46	(2.23)*
F*	Machined Slot Precision	91	0.86	-	-	77	1.46	(2.32)*
	II.. Automatic Finishing Processes							
G	Final Buffing or Equivalent	91	0.86	-	-	100	1.90	2.76 (2.58 w/o items E&F)
	III. Substitute For the Box Lock							
H**	Redesigned Lap Joint	91	0.86	75	0.71	100	1.90	3.47

* Not required if H is implemented
** Does not include E&F column

TABLE 9. COST REDUCTION FOR SCISSORS
(preliminary estimate)

Column (Table 5)	Need Fulfilled	Cost Savings: Machining (0.95/unit (%)	Machining ($)	Bench and Assemble (0.95/unit (%)	Bench and Assemble ($)	Polish ($1.90/unit) (%)	Polish ($)	Total
	I. Flexible No-flash Net Shape Process (progressive accumulation A-F)							
A	Basic Process	-	-	-	-	44	0.84	0.84
B	220Grit Finish	-	-	-	-	77	1.46	1.46
C	Machined Surfaces	40	0.38	-	-	77	1.46	1.84
D	Detail & Undercut	80	0.76	-	-	77	1.46	2.22
E	Slot Configuration		NOT APPLICABLE					
F	Machined Slot Precision		NOT APPLICABLE					
	II. Automatic Finishing Processes							
G	Final Buffing or Equivalent	80	0.76	-	-	88	1.67	2.43
	III. Substitute For the Box Lock							
H	Redesigned Lap Joint		NOT APPLICABLE					

Table [illegible] for forceps suggests that the preliminary estimate of a total cost reduction equaling $[illegible].4[illegible] offsets (by a comfortable margin) the competitive differential of $[illegible].[illegible]. The cost reduction in Table 8 is accomplished through the progressive implementation of advanced technology. If only the implementation of near net shape technology plus automated polishing is attempted, cost reduction is $2.76 - more than enough to offset the offshore price advantage. In fact, the cost reduction goal would be met even if attempts to produce the part to near net shape were not successful with respect to items E and F in Table 8 - the production of a box joint slot without machining.

Alternatively, if a redesigned lap joint could eliminate the box joint and still have the impact proposed in Table 8, the relatively complex efforts (columns E & F) to produce the slot of the box joint through net shape techniques would also no longer be needed and some additional savings would be realized through reduced benching requirements. Such a change has been proposed by the medical community on the basis of improved cleaning[1]. Changes that make the cleaning of instruments simpler and more reliable might be of interest where operations had to be carried out in the field.

In effect, the above discussion suggests that there are three strategies that meet, or exceed, the cost reduction goal established by the reported offshore price differential. Figure 14 summarizes these strategies and lists them in order of increasing complexity and cost of implementation. The estimated dollar savings are shown for each strategy.

The competitive differential for small, straight scissors was not reported during the industry review. Data in Table 9 suggest that at least a differential of $2.43 per unit might be offset by fulfilling most of the same technological needs as were considered for the forceps. It was also assumed that the manufacturing operations represented the same value with respect to the scissors as they do in the case of the forceps.

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1 Mostaffa, Chackett and Holliday, "Cleaning of Surgical Instruments with Demountable Hinge Joints", Medical and Biological Eng., Nov. 1976.

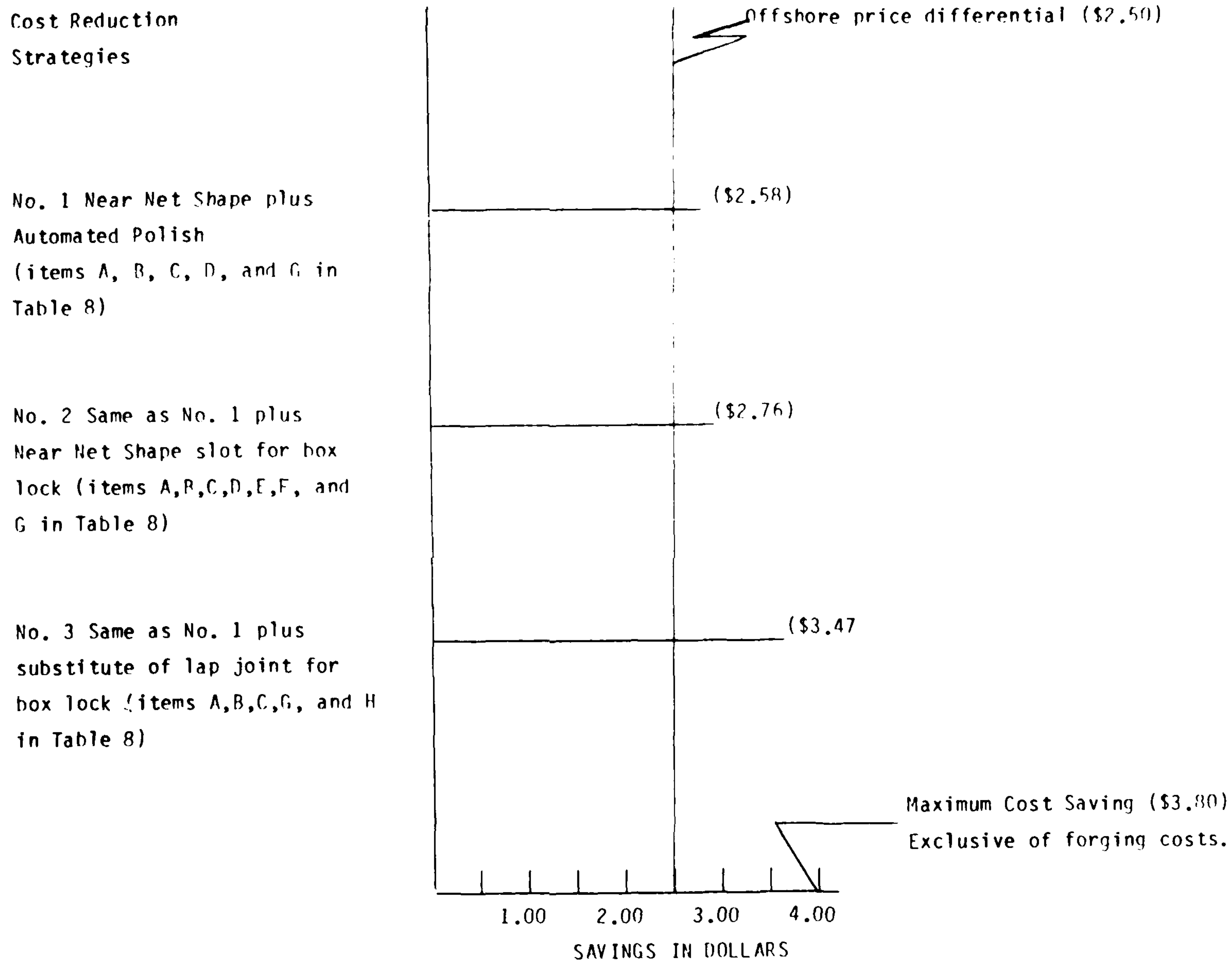

Figure 14. Summary of cost reduction strategies for simple forcepts (e.g. Kelly)

4.5 LIMITS OF THE METHOD

The above analysis provides guidance to establish which general technological thrusts must be pursued and suggests the potential for success of the advanced technology strategy. However, this preliminary effort should not be considered a business plan. A number of business issues cannot be addressed at this point. The impact of investment in new technology has not yet been identified, nor has means for encouraging such investment. Issues involving the true cost of the individual operations that have been eliminated are beyond the scope of this project. For this analysis all operations were assumed to represent an equal cost. In fact, the elimination of certain operations may provide a much greater reduction in manufacturing cost than would the elimination of others.

5. IDENTIFYING ADVANCED TECHNOLOGIES THAT WILL IMPACT COST

The most important enabling technology appears to be some sort of net shape process, with good flexibility to accommodate the low peacetime ordering quantities that were reported by the producers. Three areas of suggested process technology are precision forging, powder forming, and precision casting.

5.1 FORGING AND PRESSING

Several past attempts to forge to near-net shape were reported by planned producers during the survey for this report. Most of the advanced technology that was mentioned related to two forging processes:

Warm forging (with glass as a surface protector)

Cold Pressing using a smooth surface rod formed/ welded to produce ring fingers.

In either case, the traditional forged martensitic steel could be used and no reconsideration of the material is needed.

The problem with both processes is that flash is invariably generated. Flash necessitates the reinstatement of at least 45 percent of the polishing costs eliminated in Table 6 and 7. Additionally, dies and processing become more complex as the process attempts to develop the final net shape. Both of these trends mitigate flexibility. When flexibility cannot be used to make a specific starting shape for each item, the producer is forced to develop generic starting shapes that must be modified to final form by additional manufacturing operations. The trend contradicts the objective of eliminating as many labor intensive operations as possible.

5.2 POWDER FORMING

Powder products must have a broad, not-too-deep configuration if the punch is to compact the full depth of the powder in the die. This compacting condition could only be achieved if the direction of compaction was the same as the present forging motion. The die, into which the carefully weighed powder charge is poured, would resemble the forging die but would be several times deeper. The punch would enter the die to compact the powder. Little, if any, flash would be involved. However, the resulting "green compact" would have a D-shaped cross section because the punch face must be flat. A flat punch is required so that force can be transmitted to the powder charge across the full width of the die cavity.

Thus the initial green preform would have to be further forged to convert the D section to the symetrical cross section required in many parts of the tool. Upper and lower contoured dies could be used for the reforging. Reforging of the powder compact might be accomplished at warm temperatures to help consolidate the powder. With proper die design and control of the preform volume, the warm reforging operation might still avoid flash.

There is no potential in the powder process for the formation of the box lock slot. Nor could the undercut be applied to the ratchet teeth. The introduction of powder metallurgical techniques would permit retention of the traditional forged alloy compositions. However powder metallurgy introduces the issues of toughness/ductility and density/strength. An engineering study would be required to resolve these material issues in terms of service requirements.

5.3 PRECISION CASTING

Castings with surface finishes of 90 to 25 μ inch, tolerances of $\pm$ 0.001 inch and cross sections as thin as 0.025 inch are regularly produced by the investment (or lost-wax) process. Parts can be produced in small or large lots since each casting involves a separate easily-provided wax pattern. The wax pattern, in turn, requires a die which could be of metal (for long running items), plastic or rubber cast directly from an existing instrument.

The lost wax process has been refined to a point where precision slots can be cast into air cooled turbine blades. This technology might be evaluated to produce an as-cast box lock.

Consideration should be given to combining the lost wax pattern with solid ceramic mold technology (e.g., the Shaw Process - see SME Tool and Manufacturing Engineers Handbook). Solid ceramic molds are sometimes used to produce extrusion tools in steel. These as-cast tools are precise enough to be used without further machining and often contain surface detail as fine as natural wood grain. Tolerances for a 3 to 8 inch instrument would be $\pm$ 0.001 to $\pm$ 0.002 inch and surface finish would be 60 to 90 μ inch. However, a hard steel surface honed with the 220 grit that is characteristically used by the instrument industry results in an 18 μinch surface so that some further refinement or a secondary finishing operation would seem to be required.

5.4 PROCESS SELECTION

Table 10 is a list of objectives that must be achieved if the needs of the cost reduction program are to be met. The ability of the various candidate net shape processes to fill those needs is also assessed in Table 10.

The pressing (with looped rod preform) technology scores well when considering the desirability of staying with the established wrought materials. However, the integrity of the cross wire weld used to form the ring finger would have to be investigated. Neither pressing nor forging provides much flexibility. Thus generic designs would be required. Generic designs require extra operations to make them conform to the detailed requirements of specific parts.

TABLE 10. ABILITY OF CANDIDATE PROCESSES TO MEET MANUFACTURING OBJECTIVES IN SURGICAL INSTRUMENT MANUFACTURE

NET SHAPE PROCESS CANDIDATE	OBJECTIVES								
	FLEXIBILITY	NONFLASH	18-25 μINCH FINISH[1]	±0.002 INCH PRECISION	FINAL DETAIL	UNDERCUT RATCHET LOCKS	PRECISION SLOTS	100% DENSITY	WROUGHT METAL CHARACTERISTICS
COLD PRESSING	NO	YES	POSSIBLE	POSSIBLE	POSSIBLE	NO	NO	YES	YES
FORGING	NO	NO	NO	NO	NO	NO	NO	YES	YES
POWDER FORMING	NO	YES	POSSIBLE	POSSIBLE (Coining)[2]	YES (Coining)[2]	NO	NO	NO	NO
PRECISION CASTING	YES	YES	POSSIBLE (ceramic)[3]	POSSIBLE (ceramic)[3]	POSSIBLE (ceramic)	YES	POSSIBLE (ceramic)[4]	YES	NO

[1] *An 18 μinch finish is that which is produced when hard ferrous alloys are finished with a 220 grit* hone (ref. SME TMEH, Vol. 3, Table 16-40). A 60-90 μinch finish is similar to that produced by a 100 grit blast.

[2] Refers to coining after sintering to produce ± 0.001 inch to ±0.003 inch Tolerance (Ref. SME TMEH, Vol. 2, Table 17-5)

[3] Refers to ceramic molding techniques such as the Shaw or Unicast processes. These processes report finishes of 60-90 μinch and tolerances of ±0.003 inch (Ref. SME TMEH, Vol. 2, page 16-61).

[4] Refers to ceramic core technology. (Ref. SME TMEH, Vol. 2, pp 16-65.)

Powder forming minimizes metal flow and thus reduces or eliminates flash. A cold coining operation prior to sintering might be adopted to increase density and produce details. However, powder metal is not as dense as wrought metal. Sintered particles do not behave as solid metal under stress. Powder metal properties are acceptable for many applications, however, and an engineering study might confirm that surgical instruments were one such an application. Considerable effort might be required in punch and die design since powder compacting would have to be carried out at right angles to the long axis of the instrument. This forming complexity and the use of heavy tooling suggests that powder forming would be little better than forging/ pressing as a candidate.

Precision casting appears to be the enabling technology candidate with the best chance for success. A method that would combine the closed flask advantages of the lost wax method with the precision of ceramic molds might be the most effective.

However, even ceramic molds do not meet the estimated 18 inch surface finish requirements. As an initial step, an engineering evaluation of actual surface finish requirements seems to be needed. If the surface comes from the casting with a minimum of irregularities, buffing might be initiated without the need to bring the part through the 100 grit to 200 grit series. One producer suggested that he was only going to 120 grit prior to buffing. A 120 grit finish is equivalent to approximately 60 inch roughness. Castings can already be produced with 60 to 90 inch roughness. Thus a better engineering definition of the polishing requirement might be developed in order to determine the exact finish condition that will permit buffing.

Regardless of the net shape forming method employed, some automated method of buffing appears to be necessary to meet the full scope of the required cost reduction. Automated (NC) buffing equipment is available* and its overall effectiveness should be compared to advanced electrochemical techniques.

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*Edward Tulinski, "Automated Functional and Decorative Finishing," Final Finish Technology, Vol. 1, No. 1, January-March 1987.

6. STRATEGIES FOR DEVELOPING AND IMPLEMENTING NEW TECHNOLOGIES

In order to remove enough cost to be competitive with Pakistani instruments, data in Tables 8 and 9 suggest that the goal of any thrust should be keyed to net shape forming and automated polishing. However, most efforts in that direction will place pressure on real or imagined constraints that exist within the manufacturing community. Therefore it is believed that the initial step should be an engineering analysis program to establish the constraints that assure correct function of the instrument and discard those that are not needed.

As a precursor to an engineering program, a number of applicable specifications have been reviewed with respect to the technical constraints they impose. The specifications have been separated into three levels:

1. Materials (Table 11)
2. General (design & workmanship) (Table 12)
3. Instrument Specific (Table 13)

At least two specifications of each type are listed. In one important statement, with respect to this program, ASTM F921 "Standard Definition of Terms Relating to Hemostatic Forceps" notes "...that the box lock construction defined in this standard is the most commonly produced junction for hemostatic forceps. However, the intent is not to prohibit technological innovation or to exclude instruments manufactured with other types of pivoting features such as lap joints."

One outgrowth of the engineering program should be an attempt to modify or eliminate the box joint because of its severe impact on manufacturing operations and costs.

Many other criteria are obviously functional necessities. For example serrations would be not effective during surgery if they did not interdigitate as required by several specifications. However, much information in specifications is an attempt to document for standardization rather than specify for functional necessity. The material controls may be one such area. Many new, more formable materials are now available. Plastics can provide metal like stiffness and strength, while exhibiting greater compatibility with the environment. The engineering analysis effort should attempt to establish whether nonmetallics could be used as a second portion of this strategy.

TABLE 11. SUMMARY OF MATERIAL SPECIFICATIONS FOR SURGICAL INSTRUMENTS

ISSUED BY NUMBER	TITLE	CONTENT SUMMARY
ASTM[1] F899	Stainless Steel Billet, Bar Wire for Surgical Instruments	-Establishes four Stainless Steel Classifications: Class 3 Austenitic; Class 4 Martensitic; Class 5 Precipitation Hardening; Class 6 Ferritic. -Lists Chemical compositions and commercially recognized types plus general quality and purchasing requirements. -Lists heat treatments and required hardnesses at several tempering temperatures. -Provides examples of types of instruments for most types of steel.
ISO[2] 7153/1	Instruments for Surgery Metallic Materials Part 1: Stainless Steel	-Lists 15 stainless steel grades in three categories (austenitic, martensitic, ferritic). -Does not provide metallurgical, quality or procurement information.

1 American Society for Testing and Materials

2 International Organizations for Standardization

TABLE 12. SUMMARY OF GENERAL SPECIFICATIONS FOR SURGICAL & DENTAL INSTRUMENTS

ISSUED BY:/NUMBER	TITLE	CONTENT SUMMARY
U.S. Government GG-I-526	Instruments Dental & Surgical	-Establishes & Defines nine classes of materials: Class 1 Carbon Steel; Class 2 High Carbon Steel Class 3 Austenitic Stainless Steel; Class 4 Martensitic Stainless Steel; Class 5 Precipitation Hardening Stainless Steel; Class 6 Ferritic Stainless Steel; Class 7 Cobalt-Chrome-Tungsten Alloy; Class 8 Nonferrous Metals; Class 9 Unclassified materials. -Specifies heat treatment to maximize corrosion resistance. -Lists test for each material. -Hardness of mating surfaces shall not vary by 5 HRc points - No other hardness data. -Construction features defined: Jaw serrations must mesh; Ratchets shall be undercut; Locks (joints) can be box, screw or lap; Scissors shall have a crocus finished blade; Finish can be satin (200 emory) or mirror; Final operation is passivation for class 4 and 5 steels. -Also covers method of testing and ordering data. -Delivery (including marking and QC) as defined in detailed specifications.

TABLE 12. SUMMARY OF GENERAL SPECIFICATIONS FOR SURGICAL & DENTAL INSTRUMENTS (continued)

ISSUED BY:/NUMBER	TITLE	CONTENT SUMMARY
ASTM F921	Standard Definition of Terms Relating to Hemostatic Forceps	-Introduces concept of distal (far) end and proximal end. -Introduces shank as the part that yields (provides) configuration, length and leverage. -Allows two finishes, bright (or mirror) and satin (or black). -Specifically notes that, while box lock is most commonly used, other innovative types of joints are not prohibited. -Slatches of instrument and various types of teeth and serrations. -Limited marking procedure. No QC procedure.
ASTM F1026	General Workmanship and Performance Measurements of Hemostatic Forceps	-Notes that serrations must interdigitate (mesh). -Specifies box lock construction. Box lock opening must be of equal resistance for opening & closing and nonbinding over 90 degrees. -Specifies closure and interdigitation at first ratchet. -Specifies an "elasticity" (distortion) test. -Sketch of box lock shows where maximum 0.015 inch clearance allowed. -Limited marking instructions, no QC procedures.

TABLE 12. SUMMARY OF GENERAL SPECIFICATIONS FOR SURGICAL & DENTAL INSTRUMENTS (continued)

ISSUED BY:/NUMBER	TITLE	CONTENT SUMMARY
ISO 7151	Instruments for Surgery-Haemostatic Forceps-Requirements	-Specifies ISO Grade 4 (ISO 683/13-AISI 420). -Harden to 40-48HRC. -Mating surfaces within 4 HRC. -Lists copper sulphate & boil tests but does not require both. -Serrations must mesh. -Joint must close or open with two fingers. -Surface finish: mirror polished, reflection reducing (e.g. "satin" or "black") or coated. Satin finish involves grinding, brushing, electropolishing and also glass bead or satin brush. Mirror finish is also ground, brushed, electropolished and then "mirror buffed". -Passivation defined as electropolishing or nitric acid immersions. -Specifies elasticity testing by clamping material in jaws for 3 hr at room temp. -Does not set up marking, packaging or inspection procedures.
ISO 7741	Instruments for Surgery-Scissors and Shears-General Requirements and Test Methods	-Covers scissors and shears with and without tungsten carbide or stellite insert. -Insert instruments made from ISO 7153 Grade BG-27-4 (AISI 420A). -Noninsert instruments are made from higher carbon grade, C-28-5 (AISI 420C). -Hardness. Noninsert type 50-58 HRC Instrument 40 HRC Min. Insert 710 HV10 -Describes copper sulphate and boil tests. -Specifies both test methods for AISI 420C. Other grades tested per purchase order. -Joint must close or open with two fingers. -Surface finish can be mirror polished, reflecting reducing (matte), or coated. -Passivation can be electropolish or nitric acid immersion. -Specifies a cutting test (gauze or wet tissue paper). -Does not set up marking, packaging or inspection procedures.

TABLE 13. INSTRUMENT-SPECIFIC SPECIFICATIONS

ISSUE BY:/NUMBER	TITLE	CONTENT SUMMARY
MIL-C-37002	Clamp, Bronchus, Double Curved, Daems, 9-1/2 inch	-Specifies from Class 4 Type 410 or 420 (per GG-I-526). -Specifies 40 HRC min. -Specifies exact configuration including a drawing. -Specifies box lock tested per GG-I-526. -Specifies mirror finish. -Sets up elaborate packaging/marking. -Recognizes foreign products. -Sets up elaborate QC including AQL and defect classification.
GSA A-00511825(DM)	Interim Commercial Item Description - Forceps, Hemostatic Clip Applying, Medium Serrated Jaws, Angled	-Refers to ASTM F921 for engineering and material details. -Specifies Class 4 Martensitic SS (no grade) per ASTM F899. -Specifies 40-47 HRC. -Specifies Passivation. -Specifies copper sulfate and boil tests per GG I-526. -Specified a drug (DPSC23350) plus color coded handles. -Specifies clip bending test. -Permits mirror or matte finish (except locks & ratchet). -Box lock workmanship per ASTM F1026. -Sets up a QC system much like MIL -Requires a contractor certification. -Sets up a packaging and preservation system based. on meeting functional requirements. -Cross indexes to national stock numbers.

7. CONCLUSIONS

The application of net shape technology plus automated polishing appears to be capable of removing enough cost from the post-forging manufacturing cycle to equal the offshore price differential of $2.50 cited by the planned producer community with respect to simple instruments such as Kelly forceps.

Applying near-net shape techniques to the formation of theh box joint results in savings that exceed the reported offshore price differential by 10 percent.

Substituting a lap joint for the box lock results in savings that exceed the reported offshore price differential by 38 percent.

Eliminating the box lock hinge may be feasible. An engineering study that precedes any extensive consideration of the change is required. However, there is some evidence in existing specifications (ASTM-F921) that the box lock hinge configuration could be eliminated from forceps and there is medical evidence that such a change would simplify and improve cleaning.

Cold pressing (using a smooth, looped rod as a preform) and precison casting (possibly with some elements of the Shaw process) appear to be leading net shape candidates.

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